



Atty. Docket No.: BP0003-US


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1645
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TECH CENTER 1600/2900

Application Serial No: 10/017,445
Date Filed: December 14, 2001
Application Title: Methods For Determining Organisms Not Requiring The Separation Of Fixative Or Excess Probe
Applicants: Rigby et al.
Group Art Unit: 1645
Examiner: Sally A. Sakelaris
Certified Mail No.: 7099 3400 0007 5728 4760

Certificate of Mailing Pursuant to:
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail and addressed to: Commissioner for Patents, Washington, DC 20231 on this 10th day of March, 2003.


Brian D. Gildea
Reg. No. 39,995

Sir:

Information Disclosure Statement

In accordance with 37 C.F.R. §1.97, Applicant(s) hereby make of record the following information and publications, some of which have been identified in the International Search Report (copy attached). Copies of PTO Form 1449 and each publication listed thereon [INCLUDE REFERENCE CODE, E.G., (U.S. PATENTS: AA through AZ); (BA - BZ FOREIGN PATENTS) &/OR (CA - CZ JOURNAL ARTICLES ETC.)] accompany this statement, either in the entirety or in the relevant parts.

Fee

Since this correspondence is being mailed within 3 months of the filing date or because no Office Action on the merits has been received, it is believed that no fee is due for consideration of the documents contained herein. If however The Office determines that a fee is due for consideration of this Information Disclosure Statement, The Office is hereby authorized to deduct any other appropriate fee due from Deposit Account 02-3240.

Customer Number/Correspondence Address

If not already done, please match this application with the customer number identified below.

Customer Number: 023544



23544

PATENT TRADEMARK OFFICE

[Insert Bar Code Here]

Respectfully submitted,

Date: March 10, 2003

Brian D. Gildea
Reg. No. 39,995

Applied Biosystems
15 DeAngelo Drive
Bedford, MA 01730
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From the INTERNATIONAL SEARCHING AUTHORITY

PCTNOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

To:
BOSTON PROBES, INC.
Attn. Gildea, Brian D.
15 DeAngelo Drive
Bedford, MA 01730
UNITED STATES OF AMERICA

Date of mailing
(day/month/year)

14/02/2003

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US 01/48675

International filing date
(day/month/year)

14/12/2001

Applicant

BOSTON PROBES, INC.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Bruno Danti

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/US 01/48675	14/12/2001	15/12/2000
Applicant		
BOSTON PROBES, INC.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

METHODS FOR DETERMINING ORGANISMS

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/68 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	STENDER H ET AL: "I-124. SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF MICROORGANISMS BY FILTER-BASED IN SITU HYBRIDIZATION USING ENZYME-LABELED PEPTIDE NUCLEIC ACID PROBES" ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, vol. 100, 21 May 2000 (2000-05-21), page 408 XP000956166 ISSN: 0067-2777 abstract	1-20
X	----- -/--	21

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

27 January 2003

Date of mailing of the international search report

14/02/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

GONCALVES M L F C

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	STENDER H ET AL: "P-26. A NEW MOLECULAR METHOD FOR SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF BRETTANOMYCES IN WINE" ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, vol. 99, 31 May 1999 (1999-05-31), page 516 XP000952544 ISSN: 0067-2777	1-20
X	abstract	21
A *	PLUSKAL M ET AL: "PEPTIDE NUCLEIC ACID PROBES AND THEIR APPLICATION IN DNA AND RNA BLOT HYBRIDIZATION ANALYSIS" FASEB JOURNAL, FED. OF AMERICAN SOC. FOR EXPERIMENTAL BIOLOGY, BETHESDA, MD, US, vol. 8, no. 7, 21 May 1994 (1994-05-21), page A1264 XP000601669 ISSN: 0892-6638 abstract	1-21
P, X *	PERRY-O'KEEFE HEATHER ET AL: "Identification of indicator microorganisms using a standardized PNA FISH method." JOURNAL OF MICROBIOLOGICAL METHODS, vol. 47, no. 3, December 2001 (2001-12), pages 281-292, XP002228739 ISSN: 0167-7012 page 283 -page 284	1-21
P, X *	STENDER HENRIK ET AL: "Combination of ATP-bioluminescence and PNA probes allows rapid total counts and identification of specific microorganisms in mixed populations." JOURNAL OF MICROBIOLOGICAL METHODS, vol. 46, no. 1, 2001, pages 69-75, XP002228740 ISSN: 0167-7012 page 70 -page 71	1-21
P, A *	STENDER HENRIK ET AL: "Rapid detection, identification, and enumeration of Escherichia coli by fluorescence in situ hybridization using an array scanner." JOURNAL OF MICROBIOLOGICAL METHODS, vol. 45, no. 1, May 2001 (2001-05), pages 31-39, XP002228741 ISSN: 0167-7012	1-20
P, X	page 33	21

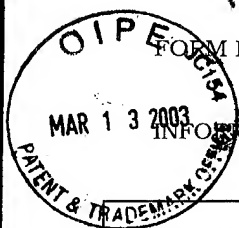
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G.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A *	STENDER HENRIK ET AL: "Rapid detection, identification, and enumeration of <i>Pseudomonas aeruginosa</i> in bottled water using peptide nucleic acid probes." JOURNAL OF MICROBIOLOGICAL METHODS, vol. 42, no. 3, November 2000 (2000-11), pages 245-253, XP002228742 ISSN: 0167-7012	1-20
X	abstract	21
Y	LUK J M C ET AL: "RAPID AND SENSITIVE DETECTION OF SALMONELLA (O: 6,7) BY IMMUNOMAGNETIC MONOCLONAL ANTIBODY-BASED ASSAYS" JOURNAL OF IMMUNOLOGICAL METHODS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 137, no. 1, 1991, pages 1-8, XP000566449 ISSN: 0022-1759 abstract	1-21
Y	US 4 591 570 A (CHANG TSE-WEN) 27 May 1986 (1986-05-27) abstract	1-21

PCT/US 01/48675

Form PCT/ISA/210 (patent family annex) (July 1992)



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: BP0003-US

APPLICANT: O'Keefe et al.

SERIAL NO.: 10/017,445

FILING DATE: December 14, 2001

GROUP: 1645

US PATENT DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AC	5,527,675	June 18, 1996	Coull et al.	435	6	Aug. 20, 1993
	AD	5,623,049	April 22, 1997	Löbberding et al.	530	300	Sep. 6, 1994
	AE	5,714,331	Feb. 3, 1998	Büchardt et al.	435	6	July 24, 1996
	AF	5,736,336	April 7, 1998	Büchardt et al.	435	6	May 1, 1997
	AG	5,766,855	June 16, 1998	Büchardt et al.	435	6	June 24, 1996
	AH	5,786,461	July 28, 1998	Büchardt et al.	536	18.7	May 1, 1997
	AI	5,837,459	Nov. 17, 1998	Berg et al.	435	6	May 24, 1996
	AJ	5,891,625	April 6, 1999	Büchardt et al.	435	6	June 7, 1993
	AK	5,972,610	Oct. 26, 1999	Büchardt et al.	530	350	Oct. 8, 1997
	AL	5,986,053	Nov. 16, 1999	Ecker et al.	536	23.1	June 7, 1995
	AM	6,107,470	Aug. 22, 2000	Nielsen et al.	536	23.1	Jan. 4, 199
	AN	6,150,097	Nov. 21, 2000	Tyagi et al.	435	6	Dec. 12, 1997

FOREIGN PATENT
DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO
	BF	WO96/40709	Dec. 19, 1996	WIPO			X

	CG	Luk, J. et al, Rapid And Sensitive Detection Of Salmonella (0:6,7) By Immunomagnetic Monoclonal Antibody-Based Assays. Journal Of Immunological Methods , 1, 1-8 (1991)					
	CH	Oliveira, K. et al. Differentiation of Candida Albicans And Candida Dubliniensis By Fluorescent In Situ Hybridization With Peptide Nucleic Acid Probes. Journal Of Clinical Microbiology , 11, 4138-4141 (2001)					
	CI	Perry O'Keefe, H. et al, Identification Of Indicator Microorganisms Using A Standardized PNA FISH Method. Journal of Microbiological Methods , 47, 281-292 (2001)					
	CJ	Pluskal, M. et al, Peptide Nucleic Acid Probes And Their Application In DNA and RNA Blot Hybridization Analysis. Journal Fed. Of American Soc. For Experimental Biology , 7, pA1264 (1994)					
	CK	Stender, H. et al, A New Molecular Method for Simultaneous Identification And Enumeration Of Brettanomyces In Wine. American Society For Microbiology , 99, p.516 (1999)					
	CL	Stender, H. et al, Combination of ATP-Bioluminescence and PNA Probes Allow Rapid Total Counts And Identification Of Specific Microorganisms In Mixed Populations. Journal Of Microbiological Methods , 1, 69-75					
	CM	Stender, H. et al, Direct Detection And Identification Of <i>Mycobacterium Tuberculosis</i> In Smear-Positive Sputum Samples By Fluorescence In Situ Hybridization (FISH) Using Peptide Nucleic Acid (PNA) Probes. Int. Tuberc Lung Dis. 9, 830-837 (1999)					
	CN	Stender, H. et al, Fluorescence In Situ Hybridization Assay Using Peptide Nucleic Acid Probes For Differentiation Between Tuberculous And Nontuberculous Mycobacterium Species In Smears Of Mycobacterium Cultures. Journal of Clinical Microbiology . Applied And Environmental Microbiology, 2, 938-941 (2001)					
	CO	Stender, H. et al, Identification of <i>Dekkera Bruxellensis</i> (<i>Brettanomyces</i>) From Wine By Fluorescence In Situ Hybridization Using Peptide Nucleic Acid Probes. Applied And Environmental Microbiology , 2, 938-941 (2001)					
	CP	Stender, H. et al, Rapid Detection, Identification, And Enumeration of <i>Escherichia Coli</i> by Fluorescence In Situ Hybridization Using An Array Scanner. Journal Of Microbiological Methods , 1 (2001)					
	CQ	Stender, H. et al, Rapid Detection, Identification, And Enumeration Of <i>Pseudomonas</i> In Bottled Water Using Peptide Nucleic Acid Probes. Journal of Microbiological Methods , 3, 245-253 (2000)					
	CR	Stender, H. et al, I-124. Simultaneous Identification And Enumeration of Microorganisms By Filter-Based In Situ Hybridization Using Enzyme-Labeled Acid Probes. American Society For Microbiology , 100, p. 408 (2000)					

EXAMINER: _____ DATE CONSIDERED: _____